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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|--------------------------|------------------------------|------------------------|
| 10/583,731 | 02/19/2008 | Bakulesh Mafatlal Khamar | 21059/0206949-us0 | 8375 |
| 7278 | 7590 | 11/10/2009 | | |
| DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770 | | | EXAMINER SWARTZ, RODNEY P | |
| | | | ART UNIT 1645 | PAPER NUMBER |
| | | | MAIL DATE 11/10/2009 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 10/583,731 | Applicant(s) KHAMAR ET AL. | |
| | Examiner Rodney P. Swartz, Ph.D. | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5-21,23,24 and 29 is/are allowed.
- 6) ☒ Claim(s) 3 and 4 is/are rejected.
- 7) ☒ Claim(s) 22,25 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 July 2009 has been entered.

Claims 1, 3, 8, 9 and 22 have been amended.

2. Claims 1-26 and 29 are pending and under consideration.

Rejections Withdrawn

3. The objection to claims 3, 8 and 9 because occurrences of "Mycobacterium w" should be in italics, is withdrawn in light of the amendment of the claims.

4. The rejection of claims 1-17, 22-26 and 29 under 35 U.S.C. 102(b) as being anticipated by Khamar et al (WO 03/049667) is withdrawn in light of the amendment of the claims and applicants' arguments.

5. The rejection of claims 1-17, 22-26 and 29 under 35 U.S.C. 102(b) as being anticipated by Khamar et al (WO 03/075825) is withdrawn in light of the amendment of the claims and applicants' arguments.

Rejections Maintained

6. The rejection of claims 18-21 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is drawn to a composition as claimed in claim 1, wherein the *Mycobacterium w* "comprises" a killed *Mycobacterium w*.

It is unclear what form of the *Mycobacterium w* is claimed due to the term "comprises". For instance, are all of the *Mycobacterium w* killed or only some of the bacteria?

Claim 4 depends from claim 3, but does not clarify the issue.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claim 22 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 22 recites: A composition containing a pharmaceutically effective amount of the composition as claimed in claim 1 sufficient to induce or enhance immunogenicity of antigen(s) when administered to a mammal.

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Claim 1 is a composition comprising three components "wherein the composition results in an enhanced antigen associated immune response of the antigen compared to a composition where component (i) is absent".

The only component of claim 22 is the composition of claim 1. By definition in claim 1, the composition is identical to claim 22 because both claims recite that the claimed composition results in induced or enhance immune response.

9. Claim 25 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 25 recites: A composition containing a pharmaceutically effective amount of the composition as claimed in claim 1 sufficient to induce or enhance immunogenicity when combined with another therapy.

Claim 1 is a composition comprising three components "wherein the composition results in an enhanced antigen associated immune response of the antigen compared to a composition where component (i) is absent".

The only component of claim 25 is the composition of claim 1. By definition in claim 1, the composition is identical to claim 25 because both claims recite that the claimed composition results in induced or enhance immune response. The recitation "when combined with another therapy" is intended use, and as such, places no further patentable distinction on claim 25.

10. Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both

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cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 26 recites: A composition containing a pharmaceutically effective amount of the composition as claimed in claim 1 sufficient to induce an immune response.

Claim 1 is a composition comprising three components "wherein the composition results in an enhanced antigen associated immune response of the antigen compared to a composition where component (i) is absent".

The only component of claim 26 is the composition of claim 1. By definition in claim 1, the composition is identical to claim 26 because both claims recite that the claimed composition induce an immune response.

Conclusion

11. Claims 3 and 4 are rejected. Claims 22, 25 and 26 are objected to.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 10, 2009